

**Appl. No.** : 10/042,775  
**Filed** : January 8, 2002  
**Response to** : Office Action dated August 24, 2004

### **REMARKS**

The Applicants have added Claims 32-36, and cancelled Claims 14 and 23-31. Thus, Claims 1-2, 5, 10-13, 15-19, 21, and 32-36 are presented for examination.

The specific changes to the amended claims are shown above in the Amendments to the Claims, wherein the insertions are underlined and the ~~deletions are stricken through~~. The Applicants respond below to rejections made by the Examiner in the Office Action of August 24, 2004.

#### **I. Interview Summary:**

An interview was conducted on Tuesday, December 7, 2004. The participants in the Interview were Examiners Gerry Leffers and Maria Marvich on behalf of the Patent Office, and attorney Mike Fuller on behalf of the Applicants. During the Interview, the participants discussed the rejections based on § 112, first paragraph for lack of written description. The participants also discussed submission of a Declaration by Applicants to demonstrate the results of using the claimed process on various types of mammalian cells.

#### **II. Allowable Claims**

The Applicants thank the Examiner for allowing Claims 1, 2, 5, 10-13, 15, and 16.

#### **III. New Claims**

The Applicants have added new Claims 32-36 which depend, either directly or indirectly, from Claim 17.

#### **IV. Rejections under 35 U.S.C. § 112**

Claims 14, 17-19, 21, and 23-31 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement.

The Examiner has rejected Claim 14, alleging that the limitation directed to the ATM protein yield is impermissible new matter because the claim is directed to L3 cells, and the yields described in the present disclosure relate only to HeLa cells. The Applicants respectfully disagree and submit that the yields stated in the present disclosure are contemplated for a variety

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of host cells. However, in the interest of advancing prosecution, Claim 14 has been cancelled, thereby rendering the rejection moot.

The Examiner has also rejected Claims 17-19, 21, and 23-31 under § 112, first paragraph, for an alleged lack of written description with respect to the ATM protein yield limitation. The Examiner admits that the present specification discloses the use of HeLa cells to obtain the claimed yields, but asserts that the disclosure of the yields of HeLa cells does not entitle the Applicants to a claim covering the genus of mammalian cells. The Applicants respectfully disagree.

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991). However, an applicant need not precisely recite each and every element of a claim limitation in the specification in order to satisfy the written description requirement. *See Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000).

The Applicants respectfully submit that the yields stated in the present disclosure are contemplated for a variety of host cells. For example, in the present specification, the Applicants state the invention preferably includes the infection of a host cell, and that “[m]ore preferably, mammalian cells and even more preferably, human cells, are infected with a recombinant viral system that expresses ATM.” *See* Specification at page 6, lines 9-11. Although the ATM protein yield is in some instances discussed with direct reference to a quantity of HeLa cells, (*See, e.g.*, Specification at page 11, lines 25-28), the specification also contains discussion of yields based on an initial mass of tissue or quantity of cells generally (*See, e.g.*, Specification at page 11, lines 21-25). Because some cell cultures are more readily measured in mass, and some are more readily measured in cell number, one of ordinary skill in the art would understand that a variety of host cell types were contemplated. The specification further states that when practicing the invention, the yield can be optimized “according to the infected host cells or tissue used.” *See* Specification at page 12, line 1). In view of the specification, one of ordinary skill would understand that such host cells could be mammalian cells, though not necessarily HeLa cells.

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Accordingly, one of ordinary skill in the art would believe that the Applicants were in full possession of the invention.

Additionally, the Applicants submit herewith, pursuant to 37 C.F.R. § 1.132, the Declaration of inventor Dr. Helen Chun, Ph.D. Dr. Chun's Declaration states that in addition to HeLa cells, Dr. Chun has performed experiments in which L3 cells and CV-1 cells were used as host cells for transfection by vaccinia virus to express ATM protein. *See* Chun Decl. at ¶ 5. Western blots of ATM protein expressed in all three types of cells are attached as Exhibits A, B, and C to the Declaration. *See* Chun Decl. at ¶¶ 6-7. Dr. Chun states, based on a visual inspection of the blots, that the levels of protein expression in all three cells lines were comparable, suggesting that the results obtained with HeLa cells were also found with L3 and CV-1 cells. *See* Chun Decl. at ¶ 8. Furthermore, Dr. Chun states that vaccinia virus is known and understood to be a highly versatile vector that is generally able to transfect nearly all types of mammalian cells, which leads her to conclude that the results obtained with HeLa cells would be seen in nearly any other type of mammalian cell. *See* Chun Decl. at ¶ 9.

The Applicants respectfully submit that the three types of cell lines, HeLa, L3, and CV-1, for which favorable results have been demonstrated, adequately represent the genus of mammalian cells in this context. Although protein expression by transfection may be considered an "unpredictable art" generally, the widely successful nature of vaccinia virus in transfecting mammalian cells leads to the conclusion that other cell types may be readily substituted for HeLa cells to obtain the high ATM yield discovered by the inventors.

Accordingly, the Applicants respectfully submit that one of ordinary skill in the art would have believed that at the time the application was filed, the Applicants were in full possession of the claimed invention. Thus, Claims 17, 19, and 21 are supported as required by § 112, first paragraph. Claims 32-36 are new and depend, either directly or indirectly from Claim 17.

In view of the above, the Applicants respectfully request that the § 112 rejections be withdrawn.

### **CONCLUSION**

The Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor,

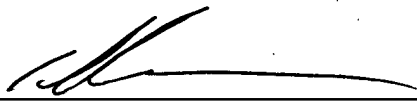
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and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art.

In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is respectfully requested. If the Examiner has any questions which may be answered by telephone, she is invited to call the undersigned directly.

Respectfully submitted,  
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Dated: 12/22/04

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